K011404

FEB 2 2 2002

SUMMARY OF SAFETY AND EFFECTIVENESS DATA RELATING TO SUBSTANTIAL EQUIVALENCE

Proprietary Name:	Fabius GS Anesthesia System
Classification Name:	Gas Machine, Anesthesia – 73 BSZ
Device Class:	Class II
Initial Distributor:	Draeger Medical, Inc. 3135 Quarry Road Telford, Pennsylvania 18969 USA
Establishment Registration No.:	2517967
Devices to which substantial equivalence is claimed:	Narkomed GS Anesthesia System – K963994 Divan Anesthesia Ventilator – K980208 Narkomed 6000 Anesthesia Workstation – K980553 Julian Anesthesia Workstation – K983635

Device Description:

The Fabius GS is a continuous flow gas anesthesia system.

Intended Use:

The Fabius GS may be used for spontaneous, manually assisted, or automatic ventilation of patients during anesthesia, and delivery of gases and anesthetic vapor. The Fabius GS can monitor inspired oxygen concentration, breathing pressure, and respiratory volume.

Substantial Equivalence:

Like the Narkomed GS, the Fabius GS is an anesthesia system with integrated monitors providing measurement and display of respiratory volume, breathing pressure, and inspired oxygen.

The principle of operation of the Fabius GS gas delivery system is similar to that of the Narkomed GS.

The Fabius GS, like the Narkomed GS, can deliver up to three gases (O_2, N_2O and Air) and one anesthetic agent. Both utilize pipeline connections and gas cylinder yokes. The Fabius GS differs from the Narkomed GS in that it does not offer pipeline connections or cylinder yokes for CO2 or Heliox.

Both the Fabius GS and Narkomed GS incorporate an RS-232 serial communication port.

The Fabius GS can accommodate up to two vaporizers (functionally) mounted on the machine while the NMGS can accommodate up to three. The Fabius GS also provides a bracket for storage of a third vaporizer on the side of the machine.

The vaporizer mounting and exclusion system of the Fabius GS is identical to NM6000 Anesthesia Workstation. Both systems prevent more than one vaporizer from being used at one time.

The Fabius GS and the Julian use thermo anemometry to measure respiratory volume. The Fabius GS ventilator and the Divan ventilator are volume or pressure preset, time cycled, pressure limited ventilators with electronic timing, pneumatic circuitry, and controls for frequency, inspiratory to expiratory (I:E) ratio, inspiratory flow rate, tidal volume and inspiratory pressure limit.

The Fabius GS ventilator and Divan ventilator provide automatic, manual, and spontaneous modes of ventilation. Ventilation settings in both ventilators are user adjustable. The Fabius GS ventilator differs from the Divan in that it is not capable of Synchronized Intermittent Manual Ventilation (SIMV) and does not provide a heater to warm the patient gas in the breathing system.

The Fabius GS ventilator and Divan ventilator are microprocessor controlled. Both display ventilator settings and utilize a keypad and incremental encoder as a user interface. The Fabius GS ventilator utilizes the keypad, incremental encoder and display integrated into the anesthesia system whereas on the Divan, the ventilator keypad, incremental encoder, and display are on the Divan front panel, separate from the anesthesia workstation controls.

The Fabius GS ventilator and Divan ventilator use a piston assembly to control the amount of tidal volume or pressure delivered to the patient during automatic ventilation based on parameters selected by the operator.

The Fabius GS ventilator and the Divan incorporate compact breathing systems. The Fabius GS breathing system is mounted on the side of the anesthesia workstation while the Divan breathing system is an integral part of the ventilator assembly. Both breathing systems include an absorber, inhalation and exhalation valves, an APL valve, a control for positive end-expiratory pressure (PEEP), a breathing bag, and connectors for an O_2 sensor, airway pressure sensor, and a flow sensor.

Qualification of the Fabius GS included hazard analysis, functional, communication, environmental, and electromagnetic compatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2002

Mr. Michael A. Kelhart
Dräger Medical, Inc.
3135 Quarry Road
Telford, PA 18969

Re: K011404
Fabius GS Anesthesia System
Regulation Number: 868.5160
Regulation Name: Gas Machine, Anesthesia
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: November 30, 2001
Received: December 3, 2001

Dear Mr. Kelhart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

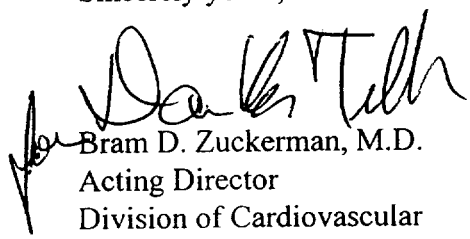
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011404

Device Name: Fabius GS Anesthesia System

Indications for Use:

The Fabius GS is indicated as a continuous flow anesthesia system. The Fabius GS can be used for spontaneous, manually assisted or automatic ventilation, delivery of gases and anesthetic vapor, and monitoring oxygen concentration, breathing pressure and respiratory volume of patients during anesthesia. Federal law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011404

(Optional Format 1-2-96)